

DEC - 7 2011 K113182

## 510(k) Summary

**Submitter:** Edwards Lifesciences® LLC

**Contact Person:** Spencer Walker, Regulatory Affairs Associate II  
12050 Lone Peak Pkwy  
Draper, UT 84020  
(801) 565-6100

**Date Prepared:** October 27, 2011

**Trade Name:** Edwards Lifesciences® IntraClude™ Intra-Aortic Occlusion Catheter

**Classification Name:** Vascular Clamp  
21 CFR Part 870.4450, Product Code DXC, Class II

**Predicate Device:** K974175: Heartport Endoaortic Clamp Catheter

### Device Description:

The IntraClude Intra-Aortic Occlusion Device is a 9 Fr (3mm), triple-lumen, 100-cm-long catheter with an elastomeric balloon near its distal tip designed to occlude the ascending aorta in order to partition the aortic root from arterial circulation during cardiopulmonary bypass (CPB). The balloon expands to occlude a range of aorta sizes from 20 to 40 mm. The shaft is provided with an extended strain relief, which tapers from 10.5 Fr to the remaining 9 Fr catheter, and is designed to prevent kinking and to avoid compressing the shaft when the hemostasis valve of an arterial cannula introducer sheath is firmly closed around the catheter body.

The large central lumen of the IntraClude catheter serves three functions: accommodating the guidewire, delivering cardioplegia solution to the aortic root, and venting fluid and air from the aortic root. The two remaining lumens serve as conduits for balloon inflation/deflation and aortic root pressure monitoring. The hub has two flexible extension tubes with an integrated luer connection to provide access for accessories. The shaft is provided with markers to indicate the insertion depth. A Clamp-Lock™ device, provided on the extended strain relief portion, allows the IntraClude catheter to be locked in position to prevent balloon migration during aortic occlusion. The devices are provided sterile and non-pyrogenic; they are intended for single use only.

### Indications For Use:

The IntraClude Intra-Aortic Occlusion Catheter is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion Catheter occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

### Comparative Analysis:

It has been demonstrated that the IntraClude catheter is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The IntraClude catheter has been fully assessed within the Edwards' Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to confirm safety and efficacy.

**Functional/Safety Testing:**

The following functional tests were performed. All data met pre-determined acceptance criteria.

- Biocompatibility – Per ISO 10993-1 for External communicating device, direct circulating blood path, duration ≤ 24 hours.
- Tensile testing – Confirmation of the bond strength of the catheter, lumens, and connected accessories.
- Flow and Venting Rates – Inspection of catheter, lumens, and accessories for cardioplegia flow and aortic root venting rates.
- Catheter Bending – Inspection of catheter, lumens, and accessories to confirm functionality after manipulation of the catheter.
- Dynamic Pressure – Confirmation of device integrity after exposure to dynamic water flow and manipulation of the catheter, lumens, and accessories.
- Balloon testing – Testing for inflation/deflation times, balloon diameter, shape, insertion/retraction force, and burst pressures.
- Design Validation – Design was validated through animal and cadaver studies.

**Conclusion:**

The IntraClude Intra-Aortic Occlusion Catheter is substantially equivalent to the cited predicate device. Additionally, the IntraClude catheter met all pre-determined acceptance criteria to confirm safety and efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

DEC - 7 2011

Edwards LifeSciences, LLC  
c/o Mr. Spencer Walker  
Regulatory Affairs Associate  
12050 Lone Peak Parkway  
Draper, UT 84020

Re: K113182  
IntraClude Intra-Aortic Occlusion Device  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II (two)  
Product Code: DXC  
Dated: October 27, 2011  
Received: October 28, 2011

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



*for* Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Statement of Indications for Use

### Indications for Use

510(k) Number (if known): K113182

Device Name: Edwards Lifesciences IntraClude Intra-Aortic Occlusion Catheter

The IntraClude Intra-Aortic Occlusion Catheter is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion Catheter occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

Prescription Use   x    
(Per 21 CFR 801.109)

OR Over-The-Counter Use                     

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office Of Device Evaluation (ODE)

M. J. Wilhelms  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K113182

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